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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

OREGON PRESCRIPTION DRUG MONITORING PROGRAM, an agency of the **STATE OF OREGON**,

Plaintiff,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, an agency of the **UNITED STATES DEPARTMENT OF JUSTICE**,

Defendant.

Case No.: 3:12-cv-02023-HA

DECLARATION OF DR. DEBORAH C. PEEL IN SUPPORT OF PLAINTIFFS-INTERVENORS' MOTION FOR SUMMARY JUDGMENT

JOHN DOE 1, et al.,

Plaintiffs-Intervenors,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, an agency of the **UNITED STATES DEPARTMENT OF JUSTICE,**

Defendant in Intervention.

I, Deborah C. Peel, MD, hereby declare and state as follows:

1. I am a medical doctor licensed in the State of Texas. For over thirty-five years, I have practiced as a boarded adult psychiatrist and Freudian psychoanalyst. I have evaluated and/or treated hundreds-thousands of patients who have taken controlled substances for many sensitive diagnoses in my private practice and as part of my job as the elected Chief of Psychiatry at Brackenridge Hospital in Austin for 11 years (1979-1990). During that time I also served as the first Director of the Central Texas Medical Foundation's Psychiatric Training Program. In that capacity, I supervised and trained dozens of psychology interns and residents from various medical specialties who provided consultation and treatment to inpatients and to Emergency Room patients. I was recognized by the American Psychiatric Association as a Distinguished Fellow in 1986, and received a Commendation from the Senate of the State of Texas "For Her Outstanding Health Care Service to the People of Texas", on March 11, 2002.

I am also the nation's leading advocate for patients' rights to control access to sensitive personal health information in electronic systems, including the Internet. I have testified on health privacy at state and federal agencies and at Congressional briefings; spoken often at national and international conferences; am quoted by major national digital and print media and

in trade journals; and have spoken as a health privacy expert on radio and on national TV network news.

In 2004, I founded Patient Privacy Rights (PPR), the nation's leading consumer health privacy advocacy organization. PPR has over 20,000 members in all 50 states. In 2007, I founded the bipartisan Coalition for Patient Privacy, representing 10.3 million US citizens who want to control the use of personal health data in electronic systems. In 2007-2008, I led the development of PPR's Trust Framework, 75+ auditable criteria[1] to measure how effectively technology systems protect data privacy. The Framework can be used for research about privacy and to certify health IT systems. In 2011, I created the International Summits on the Future of Health Privacy,[2] co-hosted by Georgetown Law Center. Last year, I proposed a 5-year plan to move the US health IT system from institutional to patient control over health data in *Information Privacy in the Evolving Healthcare Environment*.[3] A resume accurately reflecting my qualifications is attached as Exhibit A.

2. In preparing this declaration, I have read filings in the above-captioned case, including the Complaint in Intervention and the Memorandum in Support of Motion to Intervene. I have also reviewed the website of the Oregon Prescription Drug Monitoring Program. The opinions offered in this declaration are based on my own knowledge and experience, including my experience as a practicing physician and health privacy expert, my knowledge of relevant scholarly literature and the media, and my conversations with other physicians, scholars and medical privacy experts.

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[1] http://patientprivacyrights.org/wp-content/uploads/2013/04/%C2%A9-2010-to-2013-PPRs-Trust-Framework-Brief-Summary-and-Auditable-Critera.pdf

[2] http://www.healthprivacysummit.org/events/2013-health-privacy-summit/event-summary-1bfa9be80d364092aeed1a8803377fa8.aspx.

[3] http://ebooks.himss.org/product/information-privacy-in-evolving-healthcare-environment44808.

3. Knowing the prescription medications a person takes can reveal his or her underlying medical conditions, which frequently constitutes highly sensitive information. Many medications are approved for treatment of a single illness or a small number of medical conditions, so information that a person takes a particular medication often reveals the specific condition the medication has been prescribed to treat and how seriously the condition affects that person.

4. Many state Prescription Drug Monitoring Programs (PDMPs), *not* including Oregon's PDMP, currently allow broad access to identifiable patient prescriptions for controlled substances by law enforcement, the Drug Enforcement Agency (DEA), and other government agencies. (A growing number of states, like Oregon, have instituted protections against unjustified law enforcement access). This case shows the DEA's intent to access prescriptions for controlled substances in all state PDMPs, despite Americans' broad rights to health information privacy[4] [5] and despite the specific Oregon law that states law enforcement requests must be pursuant to a valid court order[6].

5. Further pressures to open access to Oregon's and other state PDMPs will continue as other state and federal agencies find more uses for information about controlled substances. For example, one reaction to Newtown is to expand efforts to collect mental health data for the FBI's National Instant Criminal Background Check System (NICS). The FBI and the Bureau of

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[4] "*The right to be let alone is the most comprehensive of rights and the right most valued by civilized men.* To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the [Constitution]." *Olmstead v. United States*, 277 U.S. 438, 478, 48 S.Ct. 564, 572 (1928) (Brandeis dissenting) (emphasis added).

[5] "In fact, *the constitutionally protected right to privacy of highly personal information is so well established that no reasonable person could be unaware of it.*" *Sterling v. Borough of Minersville*, 232 F.3d 190, 198 (3d Cir. 2000) (emphasis added).

[6] Oregon Prescription Drug Monitoring Program, see: http://www.orpdmp.com/orpdmpfiles/PDF_Files/PDMP_FactSheet_2012_v1.1.pdf.

Alcohol, Tobacco, Firearms and Explosives (ATF) also are encouraging states to collect and provide "all relevant mental health information" necessary for a background check to identify persons who are prohibited from purchasing firearms. Information about people who have been committed for treatment for addiction or substance abuse is required for the NICS; it's not a big leap to imagine the FBI and ATF pursuing information about people who are treated for withdrawal from alcohol or heroin addiction with controlled substances.

6. Controlled substances are used to treat many very sensitive, stigmatized, or embarrassing conditions and diagnoses such as addiction or substance abuse, nausea and vomiting in cancer patients, gender disorders, anxiety disorders, chronic pain, seizure disorders, and obesity.

7. Drugs listed in schedules II through IV under the federal Controlled Substances Act are used to treat a wide range of medical conditions that patients find potentially embarrassing, sensitive, or stigmatizing. Based on my review of drugs listed in schedules II-IV, medical conditions treated by these drugs include:

a. Hormone replacement therapy for treatment of gender identity disorder/gender dysphoria: testosterone

b. Weight loss associated with AIDS: Marinol (dronabinol), Cesamet (nabilone) (synthetic cannabanoids used to stimulate appetite)

c. Nausea & vomiting in cancer patients undergoing chemotherapy: Cesamet (nabilone), Marinol (dronabinol)

d. Trauma- And Stressor-Related Disorders[7] includes Acute Stress Disorder and Post Traumatic Stress Disorder (PTSD) : Xanax, Valium, Ativan, Lexotan, Librium, Traxene, Sepazon, Serax, Centrax, nordiazepam

e. Anxiety disorders and other disorders with symptoms of panic, including Separation Anxiety Disorder, Panic Disorder, Agoraphobia, Specific Phobia, Social Anxiety Disorder/Social Phobia, generalized Anxiety Disorder, Anxiety Disorder Associated with Another Medical Condition, and Anxiety Disorder Not Elsewhere Classified: Xanax, Valium, Ativan, Lexotan, Librium, Traxene, Sepazon, Serax, Centrax, nordiazepam

f. Alcohol addiction withdrawal symptoms: Serax/Serenid-D, Librium (chlordiazepoxide)

g. Heroin addiction treatment: methadone

h. Attention deficit hyperactivity disorder: Ritalin, Adderol, Vyvanse

i. Obesity (weight loss drugs): Didrex, Voranil, Tenuate, mazindol

j. Chronic or acute pain: narcotic painkillers such as codeine (including Tylenol with codeine), hydrocodone, Demerol, morphine, Vicodin, and oxycodone (including Oxycontin and Percocet)

k. Epilepsy and Seizure disorders: Nembutal (pentobarbital), Seconal (secobarbital), clobazam, clonazepam, Versed

l. Testosterone deficiency in men: ethylestrenol (Maxibolin, Orabolin, Durabolin, Duraboral)

m. Delayed puberty in boys: Anadroid-F, Halotestin, Ora-Testryl

[7] See changes from DSM IV to DSM V at: http://www.dsm5.org/Documents/changes%20from%20dsm-iv-tr%20to%20dsm-5.pdf.

n. Narcolepsy: Xyrem, Provigil

o. Insomnia: Ambien, Lunesta, Sonata, Restoril, Halcion, Doral, Ativan, ProSom, Versed

p. Migraines: butorphanol (Stadol)

8. These conditions listed above are among some of the most frequently diagnosed in Americans. Below are statistics about the incidence of common medical diagnoses that often require prescriptions for controlled substances for effective treatment:

- According to the Institute of Medicine, approximately 1/3 of the US population, or 116 million adults, suffered from chronic pain in 2011.[8]
- Migraines and other pain conditions: According to the 2009 National Health Interview Survey, 48% percent adults experienced a migraine or severe headache in the 3 months prior to the interview[9]. According to the Centers for Disease Control (CDC) Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2009[10] the crude percentage of persons in the US suffering from migraines or severe headaches, and pain in the neck, lower back, face, or jaw is 15.8% per year.
- In 2012, 240.9 million opioid prescriptions were prescribed. The number of opioid prescriptions increased 33% from 2001.[11]
- Trauma- And Stressor-Related Disorders includes Acute Stress Disorder and Post Traumatic Stress Disorder (PTSD), affecting about 7.7 million American adults[12].

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[8] Institute of Medicine, Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research (June 2011), available at http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx.

[9] http://www.painmed.org/patientcenter/facts_on_pain.aspx#hhs.

[10] http://www.cdc.gov/nchs/data/series/sr_10/sr10_249.pdf. See Table VIII. page 168

[11] http://www.nytimes.com/interactive/2013/06/23/sunday-review/the-soaring-cost-of-the-opioid-economy.html?ref=sunday-review.

- Anxiety disorders[13] are also very prevalent, annually affecting approximately 40 million adults or 18% of adults 18 years and older in the US[14], according to the NIH. The 2005 National Comorbidity Survey Replication found a higher incidence rate than the NIH: 54.7 million Americans annually were affected by the most common forms of anxiety disorder (listed below):
    - Panic Disorder, a specific type of Anxiety Disorder, affects 6 million American adults.[15].
    - Social Phobia affects about 15 million American adults[16].
    - Specific Phobias affect an estimated 19.2 million adult Americans[17].
    - Generalized Anxiety Disorder affects about 6.8 million American adults[18].
    - Separation Anxiety Disorder, one of the most common childhood anxiety disorders had a reported prevalence ranging from 3.5% to 5.4% of children in

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[12] Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Archives of General Psychiatry*, 2005 Jun;62(6):617-27.
[13] See changes from DSM IV to DSM V at: http://www.dsm5.org/Documents/changes%20from%20dsm-iv-tr%20to%20dsm-5.pdf.
[14] National Institute of Mental Health, http://www.nimh.nih.gov/health/publications/anxiety-disorders/index.shtml.
[15] Ibid.
[16] Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Archives of General Psychiatry*, 2005 Jun;62(6):617-27.
[17] Ibid.
[18] Ibid.

2000[19]. In 1990, Bowen et al reported a 2.4% overall prevalence rate of school refusal and separation anxiety disorder[20].

- Epilepsy and Seizure Disorders: Epilepsy and seizure disorders affect nearly 3 million Americans annually. Ten percent of the American population will experience a seizure in their lifetime[21].
- Attention Deficit Hyperactivity Disorder (ADHD): the CDC estimates that 5.2 million children aged 3-17 years of age have ever received a diagnosis of ADHD[22]
- Insomnia: The 2005 NIH State-of-the-Science Conference found approximately 10% prevalence of insomnia[23]. A 1991 general consensus of population-based studies of adults from many countries reported that 30% experienced one or more of the symptoms of insomnia: difficulty initiating sleep, difficulty maintaining sleep, waking up too early, and in some cases, nonrestorative or poor quality of sleep[24].
- Narcolepsy with cataplexy is estimated to affect about one in every 3,000 Americans[25].

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[19] Childhood Anxiety Disorders, by Susan Jo Perlmutter, M.D at: http://www.acnp.org/g4/GN401000163/CH159.html.

[20] Bowen RC, Offord DR, Boyle MH. The prevalence of overanxious disorder and separation anxiety disorder: results from the Ontario Child Health Study. *J Am Acad Child Adolesc Psychiatry*. Sep 1990;29(5):753-8. [Medline].

[21] http://www.epilepsyfoundation.org/aboutepilepsy/whatisepilepsy/statistics.cfm

[22] http://www.cdc.gov/nchs/fastats/adhd.htm.

[23] Sleep; National Institutes of Health State of the Science Conference Statement on Manifestations and Management of Chronic Insomnia in Adults; June 13–15, 2005; 2005. pp. 1049–57. [PubMed].

[24] Ancoli-Israel S, Roth T. Characteristics of insomnia in the United States: results of the 1991 National Sleep Foundation Survey. I. Sleep. 1999;22(Suppl 2):S347–53. [PubMed].

[25] Narcolepsy Fact Sheet, see; http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm.

9. The diseases and conditions treated with controlled substances are so common that it's likely the state PDMPs will soon contain sensitive information about the majority of Americans.

10. In the US, the strongest protections in state and federal law cover only a handful of 'sensitive' diagnostic categories (Mental Illnesses, Alcoholism and Substance Abuse Disorders, and Sexually Transmitted Diseases) and genetic information. Legislative action to protect the categories of sensitive information by restricting disclosure of that information without patient consent reflects the extremely embarrassing and/or stigmatizing responses much of the public feels about people with these conditions. In the case of genetic information, genomes, and DNA, our laws reflect individuals' feelings that genetic information is almost sacred, intensely personal, extremely revealing, and also uniquely identifies them.

11. Having treated thousands of people with sensitive, stigmatizing diagnoses, often with underlying genetic bases, I also advised and helped them to minimize or prevent sensitive information from being seen by employers, insurers, and others who may react negatively to information about mental illness or substance abuse/addiction.

12. In the Age of Paper, when records existed in only a few places (doctor's offices, hospitals, labs), it was much easier to protect sensitive health information from exposure. Even then many patients reported their mental health records were shared with employers and insurers, leading to job loss, discrimination, and reputational harms.

13. Increasingly sensitive health records are created and held in electronic systems, risking levels of exposure and harm that are truly incalculable, because it's not possible to know where your health data is held or used, or how many thousands of people have accessed it.

Sensitive electronic health records in data bases are far more vulnerable to misuse, exposure, and sale than paper medical records locked in filing cabinets.

14. There is no health data map to track the hundreds-thousands of hidden users and sellers of sensitive health data. Professor Latanya Sweeney of Harvard built and presented a first version of a health data map, but so much more is needed[26] [27] [28]. Americans have no 'chain of custody', so all the disclosures and sales of electronic records by thousands of providers, covered entities, business associates, and subcontractors are hidden. Today's electronic systems don't allow patients to control who can see or use their health data, so systems are not transparent or accountable.

15. Most sensitive health data, i.e., data about mental health and addiction, genetics, and STDs, are protected by strong state and federal laws that restrict access and/or require consent for disclosure. For example: all 50 states have laws that state psychiatric records can only be disclosed to other physicians if patients give consent, because many physicians are uncomfortable, fearful, or openly dislike patients with mental illness or substance abuse diagnoses. Information about another person's sexuality, gender identity, or gender-identity change is also extremely sensitive information which is often very disturbing to other people, making them fearful or threatening deeply-held beliefs and values. People with these conditions have very strong interests in keeping that information private, but current electronic systems make it impossible. Today, no prescription, no lab test, no office or hospital treatment can be

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[26] See thedatamap.org.

[27] Bloomberg Businessweek: "States' Hospital Data for Sale Puts Privacy in Jeopardy" by Jordan Robertson, June 5, 2013. See: http://www.businessweek.com/news/2013-06-05/states-hospital-data-for-sale-leaves-veteran-s-privacy-at-risk.

[28] See Prof Sweeney explain the concept of the data map via video at: http://www.healthprivacysummit.org/events/2013-health-privacy-summit/custom-147-1bfa9be80d364092aeed1a8803377fa8.aspx.

kept private if it's in electronic form. The only way to keep information about sensitive conditions private in electronic systems is not to seek treatment.

16. In this case, information about Plaintiffs-Intervenors' prescriptions reveals sensitive details of their diagnoses. In particular, the testosterone prescriptions used to treat John Does 2 and 4's Gender Dysphoria and the alprazolam prescription used to treat John Doe 3's Anxiety Disorder and Post Traumatic Stress Disorder reveal information that most patients reasonably wish to keep confidential.

17. Diagnoses and medications that reveal evidence of a person's sexual orientation, sexual preferences, gender identity, and/or sexual behavior (such as Sexually Transmitted Diseases), and mental illness and addiction diagnoses frequently cause social rejection and discrimination. Evidence of broad public agreement about the sensitivity and need for heightened privacy protections to prevent misuse of information about these diagnoses is reflected in strong state and federal statutes and regulations, including:

- Federal and state laws that protect information about sexually transmitted diseases such as HIV/AIDS reflect the continuing prevalence of severe stigma against homosexuality and certain kinds of sexual behavior despite greater societal acceptance of differences in sexual orientation. Laws are intended to prevent discrimination.
- Most states have very strong privacy protections for medical records and require patient consent before paper or electronic records of psychiatric treatment can be disclosed *to other physicians*.
- The federal Substance Abuse Confidentiality Regulations, known as 42 CFR Part 2, ensure that treatment records about substance abuse and/or addiction involving illegal

substances cannot be disclosed without the patient's consent[29]. Congress concluded that the greater public good was to ensure that people suffering from these conditions would seek treatment instead of being charged with crimes.

- The federal regulation known as 38 USC 7332: Medical records relating to drug abuse, alcoholism, or alcohol abuse, infection with the human immunodeficiency virus (HIV) or sickle cell anemia[30] allows members of the military to prevent the disclosure of certain kinds of sensitive information such as HIV/AIDS when they seek care outside the military health system.

18. Based on my experience as a practicing physician and my expertise in medical privacy issues, there is a strong"chilling effect" on both doctors and patients when law enforcement authorities have easy access to prescription records for controlled substances. In particular, easy law enforcement access affects patients' willingness to take controlled substances and prescribing physicians' willingness to prescribe those medications[31]. Both parties feel criminalized.

19. In 2005, Richard and Reidenberg found that physicians' concerns about being disciplined for prescribing opioids for patients in pain was a cause for undertreatment of pain[32], yet the actual risk of being disciplined by a state medical board for using opioids to treat a patient with for pain medical was virtually nonexistent. Interestingly they found that no physician was

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[29] See: http://www.samhsa.gov/about/laws/SAMHSA_42CFRPART2FAQII_Revised.pdf.
[30] http://codes.lp.findlaw.com/uscode/38/V/73/III/7332.
[31] "a significant number of physicians in this survey revealed opiophobia (prejudice against the use of opioid analgesics)" in Physicians' attitudes toward pain and the use of opioid analgesics: results of a survey from the Texas Cancer Pain Initiative. Weinstein SM, Laux LF, Thornby JI, Lorimor RJ, Hill CS Jr, Thorpe DM, Merrill JM. South Med J. 2000 May;93(5):479-87.
[32] The risk of disciplinary action by state medical boards against physicians prescribing opioids Richard J, Reidenberg MM. J Pain Symptom Manage. 2005 Feb;29(2):206-12.

disciplined solely for overprescribing opioids[33]. Earlier, in 2003 and 2004 Jung and Reidenberg reached the same conclusion: "the risk of civil, criminal, or administrative action being taken by the DEA against a physician for prescribing opioids for a chronic pain patient is small."[34] Without judicial oversight to ensure carefully targeted access to PDMPs based on probable cause, the use of PDMPs by the DEA and other law enforcement agency access will exponentially grow, because electronic systems make surveillance much faster, easier, cheaper, and more intrusive than surveillance of systems composed of paper prescription records.

20. We are facing two major US public health crises: an epidemic of prescription drug abuse and an epidemic of undertreated pain. As Fishman, et al concluded in 2004, "These are fundamentally important issues whose policy solutions have been frequently contradictory. This conflict has resulted in a variety of regulations that are intended to prevent drug abuse, but have inadvertently created barriers to the appropriate treatment of pain".[35] In 2005, Joseph A. Califano, Jr., Chairman and President of the National Center on Addiction and Substance Abuse at Columbia University noted sharply rising abuse and addiction of controlled prescription drugs-opioids, central nervous system depressants and stimulants. Two years later, he cited statistics showing escalating prescription drug abuse, increasing emergency department visits, and unintentional deaths due to prescription controlled substances.

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[33] The risk of disciplinary action by state medical boards against physicians prescribing opioids Richard J, Reidenberg MM. J Pain Symptom Manage. 2005 Feb;29(2):206-12.

[34] The risk of action by the Drug Enforcement Administration against physicians prescribing opioids for pain. Jung B, Reidenberg MM. Pain Med. 2006 Jul-Aug;7(4):353-7.

[35] Regulating Opioid Prescribing Through Prescription Monitoring Programs: Balancing Drug Diversion and Treatment of Pain. Fishman S, et al. Pain Medicine Volume 5•Number 3•2004

21. By 2007, Americans were using 80% of world's supply of all opioids and 99% of hydrocodone[36]. In 2013 the National Alliance for Model State Drug Laws and the National Safety Council called prescription drug abuse "the fastest growing drug problem in the Nation….Statistic after statistic confirmed reports that the problem had reached significant proportions"[37]. States' response to the current epidemic of prescription opioid abuse has primarily been to build PDMPs. **47 states currently allow law enforcement access to state PDMPs[38]**. As of December 2012, only Missouri and the District of Columbia lacked PDMPs[39]. But, because "a PMP is an information tool that serves the needs of criminal justice and health care professionals, federal, state, and local leaders seek to optimize multi-disciplinary use of the database[40]".

22. I agree with Manchikanti, who states the "fundamental flaw with these programs (PDMPs) is that they are created to help law enforcement identify and prevent prescription drug diversion after the fact. The secondary objective of this program, to educate and provide information to physicians, pharmacies and the public has been neglected. Very few programs are proactive to the extent that physicians can access the necessary information to reduce or prevent

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[36] National drug control policy and prescription drug abuse: facts and fallacies. Manchikanti L. Pain Physician. 2007 May;10(3):399-424.

[37] Prescription Drug Abuse, Addiction and Diversion: Overview of State Legislative and Policy Initiatives, a Three Part Series, Part 1: State Prescription Drug Monitoring Programs (PMPS) prepared by the National Alliance For Model State Drug Laws and the National Safety Council, See: page 4.
http://www.namsdl.org/IssuesandEvents/NAMSDL%20With%20the%20National%20Safety%20Council%20Part%201%20State%20PMPs%2C%20May%202013.pdf.

[38] Ibid See: page 14.

[39] Prescription Drug Abuse, Addiction and Diversion: Overview of State Legislative and Policy Initiatives, a Three Part Series, Part 1: State Prescription Drug Monitoring Programs (PMPS) prepared by the National Alliance For Model State Drug Laws and the National Safety Council. See: page 6.
http://www.namsdl.org/IssuesandEvents/NAMSDL%20With%20the%20National%20Safety%20Council%20Part%201%20State%20PMPs%2C%20May%202013.pdf.

[40] Ibid. See: page 11.

abuse and diversion"[41]. The Oregon PDMP is attempting focus on much-needed prevention of opioid abuse and addiction by prioritizing physician and pharmacist access to the PDMP, while limiting law enforcement access to selected records based on probable cause.

23. **Unfortunately a national strategy of "optimizing multi-disciplinary use' of databases of controlled substances**:

- Conflicts with patients' rights to health information privacy, creating reluctance to seek treatment and decreased access to treatment often individuals' needs for treatment.
- Causes physician reluctance to prescribe opioids even when medically appropriate[42].
    - Most Wisconsin physicians in a 2010 study felt it "acceptable medical practice to prescribe opioids for chronic cancer pain, but only half held this view if the pain was not related to cancer". Fewer were willing to prescribe "if the patient had a history of substance abuse". "2/3 were not concerned about being investigated for prescribing opioids, but some admitted that fear of investigation led them to lower the dose prescribed, limit the number of refills, or prescribe a Schedule III or IV rather than a Schedule II opioid" [43].
    - Some prescribers who legitimately administered opioids to chronic pain patients have been labeled as 'misprescribers'; California and Texas had to pass

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[41] National Drug Control Policy and Prescription Drug Abuse: Facts and Fallacies. Manchikanti L. Pain Physician 2007; 10:399-424.

[42] Influences of attitudes on family physicians' willingness to prescribe long-acting opioid analgesics for patients with chronic nonmalignant pain. Nwokeji ED, Rascati KL, Brown CM, Eisenberg A. Clin Ther. 2007;29 Suppl:2589-602. doi: 10.1016/j.clinthera.2007.12.007.

[43] Opioid analgesics for pain control: Wisconsin physicians' knowledge, beliefs, attitudes, and prescribing practices.
Wolfert MZ, Gilson AM, Dahl JL, Cleary JF. Pain Med. 2010 Mar;11(3):425-34. doi: 10.1111/j.1526-4637.2009.00761.x. Epub 2009 Dec 9.

intractable pain laws to ensure physicians would be able to prescribe opioids for chronic pain[44].

- A substantial number of physicians are unwilling to prescribe opioids in compliance with the new FDA aggressive Risk Evaluation and Mitigation Strategies (REMS), which could have the unintended effect of decreasing access to these medications for legitimate medical purposes[45].
- "PMPs are believed to have adverse effects on the legitimate prescribing of controlled substances, including the inappropriate substitution of nonregulated drugs" [46] [47]. Some physicians don't want extra paperwork and/or regulatory scrutiny[48], or worry that stocking controlled substance prescription pads will lead to burglaries, after all drugs needing a special prescription are more valuable to thieves, more dangerous, and should be avoided[49]. Fear of excessive law enforcement scrutiny adds another disincentive to legitimate prescribing of controlled substances.

- **Interferes with patient trust in physicians**

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[44] Opioids, chronic pain, and the law. Clark HW, Sees KL. J Pain Symptom Manage. 1993 Jul;8(5):297-305.
[45] Primary care physician opinion survey on FDA opioid risk evaluation and mitigation strategies. Slevin KA, Ashburn MA. J Opioid Manag. 2011 Mar-Apr;7(2):109-15.
[46] Programs for monitoring inappropriate prescribing of controlled drugs: Evaluation and recommendations. Collins T, Zimmerman D.Am J Hosp Pharm 1992;49:1765–8.
[47] The influence of multiple copy prescription on analgesic utilization. Wastila L, Bishop C. J Pharm Care Pain Symptom Control 1996;4:5–19.
[48] The patient's perspective. Berner R. N Y State JMed 1991;91(11 suppl):37S–39S.
[49] Regulating Opioid Prescribing Through Prescription Monitoring Programs: Balancing Drug Diversion and Treatment of Pain. Fishman S, et al. Pain Medicine Volume 5, Number 3, 2004

- Patients fear loss of privacy and stigmatization when their names and contact information are tracked in data bases for controlled substance prescriptions[50] [51] [52]
- "Physicians must seek to protect patient privacy in all of its forms, including (1) physical, which focuses on individuals and their personal spaces, (2) informational, which involves specific personal data, (3) decisional, which focuses on personal choices, and (4) associational, which refers to family or other intimate relations. Such respect for patient privacy is a fundamental expression of patient autonomy and is a prerequisite to building the trust that is at the core of the patient-physician relationship."[53] Physicians should inform patients that they have no choice about access by various parties to their controlled substance prescriptions.

- **Overrides physicians' ethical duties to protect the privacy of prescriptions**
  - "The physician should not reveal confidential communications or information without the consent of the patient, unless provided for by law or by the need to protect the welfare of the individual or the public interest."[54] The DEA plan to obtain the protected health information of people with a prescription in the Oregon PDMP without demonstrating probable cause to a judge does not protect

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[50] The patient's perspective. Berner R. N Y State JMed 1991;91(11 suppl):37S–39S.
[51] Benzodiazepines and triplicate prescriptions: New York's experience. Uzych L. Tex Med 1991; 87:6.
[52] Triplicate prescription: Issues and answers. Introduction. NY State J Med 1991;91(11 suppl):1S–4S. Farnsworth P.
[53] AMA Code of Medical Ethics, Opinion 5.059 - Privacy in the Context of Health Care. See: http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion5059.page.
[54] AMA Code of Medical Ethics, Opinion 10.01 - Fundamental Elements of the Patient-Physician Relationship. See: http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion1001.page.

patients' welfare or protect the public interest. Following Oregon law and requiring court orders based on probable cause would protect the privacy of a majority of Oregon residents who take controlled substances.

- "Physicians also should be mindful of patient privacy, which encompasses information that is concealed from others outside of the patient-physician relationship." [55] The DEA demands that prescriptions for controlled substances held by the Oregon PDMP be disclosed to the DEA for surveillance violate the public's expectation that law-abiding citizens should be 'let alone' and data surveillance should be carefully targeted and based on probable cause.

- **Justifies the "War on Drugs":** law enforcement actions to stop or prevent drug diversion, increased law enforcement scrutiny of prescribers, and increased use of PDMPs, instead of comprehensive proactive educational measures to prevent addiction to opioids, harms public health.

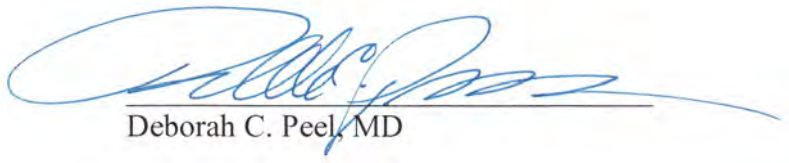
24. Physicians' ethical and professional duty of confidentiality exists precisely to protect the kind of sensitive medical information at issue in this case. Easy law enforcement access to confidential and sensitive prescription records has adverse effects for both patients and doctors, and violates the privacy that most patients and practitioners expect for protected health information.

25. Moreover, the website of the Oregon Prescription Drug Monitoring Program makes strong, clear representations about the privacy and security of prescription records, explicitly assuring patients that law enforcement can only access their records with a court order

[55] AMA Code of Medical Ethics, Opinion 5.059 - Privacy in the Context of Health Care. See: http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion5059.page.

based on probable cause. In my opinion, it is reasonable for patients in Oregon to rely on these representations in assessing the privacy of their prescription information.

Pursuant to 28 U.S.C. § 1746, I hereby declare and state under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.



Deborah C. Peel, MD

Dated: June 30, 2013

EXHIBIT A

Deborah C. Peel, MD

Founder and Chair, Patient Privacy Rights

Dr. Peel has been practicing as a physician and psychoanalyst for over thirty years. She is a leading national and international advocate for patients' rights to control access to sensitive personal health information. She began working on health privacy rights when the1993 Clinton Healthcare Initiative proposed including every doctor-patient visit in a national health data base, even if patients paid out-of-pocket to keep sensitive treatment information private.

In 2004, she formed Patient Privacy Rights (PPR), http://www.patientprivacyrights.org, which has become the nation's and the world's leading consumer health privacy advocacy organization. PPR has over 20,000 members in all 50 states.

Coalition for Patient Privacy (founded 2006)—represents 10.3 million Americans

- Leads the Coalition for Patient Privacy, a bipartisan group of over 50 national organizations from across the political spectrum, in urging Congress to add basic privacy protections to all health IT legislation. The Coalition represents 10.3 million Americans. In 2007, Microsoft Corporation joined the Coalition. The Coalition put patients' rights to privacy on Congress' agenda. The Coalition's privacy principles form the core consumer protections in ARRA/HITECH. For more information see: http://www.patientprivacyrights.org/site/PageServer?pagename=PrivacyCoalition
- The Coalition's 2009 letter to Congress resulted in historic new privacy rights being added to the stimulus bill; including a ban on sales of protected health information (PHI) without consent, audit trails for disclosures of PHI, the ability to segment sensitive PHI, breach notice, the right to block disclosure of PHI for healthcare operations if treatment is paid for out-of-pocket, and requiring technologies to make PHI unreadable or indecipherable. http://patientprivacyrights.org/media/CoalitionPatPriv_Final01.14.09.pdf

International Summits on the Future of Health Privacy:

In 2011, Dr. Peel created the first International Summit on the Future of Health Privacy, the first global public forum on the future of health privacy. Each year, summit speakers include top privacy experts from government, the private sector, academia, and advocacy, assuring discussions that include wide perspectives on urgent privacy issues and solutions. The O'Neill Institute for National and Global Health Law at Georgetown Law Center in Washington, DC co-hosts the event each year. http://www.healthprivacysummit.org/.

The keynote speakers at the June 5-6, 2013 summit on "The Value of Health Data vs. Privacy — How Can the Conflict Be Resolved included Peter Hustinx, the EU Data Protection Supervisor; Todd Park, US Chief Technology Officer; Leon Rodriguez, Director of the Office of Civil Rights, HHS; Mark Rotenberg, Director of the Electronic Privacy Information Center; and Prof Melvin Urofsky, Louis D. Brandeis' biographer.

First Tocker Fellow at the University of Texas School of Information (2011-2012)
http://www.ischool.utexas.edu/about/news/view_news_item.php?ID=363

Wall Street Journal Debate on Unique Patient Identifiers:

- "Should Every Patient Have a Unique ID Number for All Medical Records?" January 23, 2012 (58% of online voters supported Dr. Peel's position opposing unique patient IDs): http://online.wsj.com/article/SB10001424052970204124204577154661814932978.html

Wall Street Journal op-ed

- "Your Medical Records Aren't Secure", 3/24/2010 http://online.wsj.com/article/SB10001424052748703580904575132111888664060.html

White Paper

- "The Case for Informed Consent" by Deborah C. Peel, MD and Ashley Katz, August 31, 2010 at: http://patientprivacyrights.org/2010/08/the-case-for-informed-consent/

Congressional Briefings

- Congressional Briefing with Congressmen Barton and Markey: "Three Years After HITECH, Can Patients Control The Use Of Personal Health Data Yet? June 7, 2012
- Health Affairs briefing, Stimulating Health Information Technology, March 10, 2009
- Alliance for Healthcare Reform, Health IT and Privacy: Is there a Path to Consensus? February 29, 2008
- Congressional Internet Caucus: 4th Annual State of the Net Conference, January 30, 2008
- Connecting for Health, Roundtable Discussion on HIT and Privacy, April 13, 2007
- Trusted Third Parties for Personal Health Records & Patient Privacy Briefing, sponsored by Patient Privacy Rights, The Heritage Foundation, and the Progressive Policy Institute, December 15, 2006
- Medical and Dental Doctors in Congress Caucus: Briefing on HIT by Former Speaker Newt Gingrich, Representative Patrick Kennedy, and Deborah Peel, MD, June 21, 2006
- Briefing on Health IT and Patient Privacy: Hear from Medical and Technology Experts on How Health IT Can Preserve Privacy While Improving Care, June 9, 2006
- 21st Century Healthcare Caucus– Protecting Patient Privacy in a Digital Healthcare Age, Briefing on Privacy and HIT, Nov 17, 2005

Federal and Congressional Testimony

- HHS: HIT Policy Committee, PCAST WG, Panel 2: Patients, Consumer, Privacy Advocates, February 15, 2011 http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3354&PageID=21743#021511
- HHS: Consumer Choices Technology Hearing, Discussant, June 29, 2010, http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=2833&PageID=19477
- Exploring Privacy: An FTC Roundtable Discussion, Panel 2 Health Information, March 17, 2010 http://http.earthcache.net/htc01.media.qualitytech.com/COMP008760MOD1/FTC2/031710_ftc_sess3/index.htm
- HIT Policy Committee, Testimony on Privacy, September 18, 2009 http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11113_889203_0_0_18/Peel_PPR%20Written%20testimony%20HIT%20Policy%20Committee.pdf and http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11113_889204_0_0_18/Peel2_Protection%20of%20Right%20to%20Privacy%20for%20HITSP.pdf
- NCVHS Panel, Testimony on PHRs, June 9 , 2009 http://www.ncvhs.hhs.gov/090609p8.pdf
- House Energy and Commerce Committee, Subcommittee on Health, Testimony on Health Information Privacy, June 4, 2008 http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/Testimony/HE/110-he-hrg.060408.Peel-Testimony.pdf
- IOM Committee on Health Research and Privacy of Health Information, October 1, 2007 http://www.iom.edu/~/media/Files/Activity%20Files/Research/HIPAAandResearch/PeelIOMResearchHIPAA2.pdf
- NCVHS Panel, Testimony on Uses of Health Data, August 2, 2007 http://ncvhs.hhs.gov/070802tr.htm
- House Energy and Commerce Committee, Health Subcommittee, Written Testimony on Health IT and Privacy March 16, 2006
- House Judiciary Committee, Subcommittee on the Constitution, Testimony on Genetic Privacy, Sept 12, 2002 www.house.gov/judiciary/peel091202.htm
- Senate HELP Committee, Written Testimony on Medical Privacy, April 16, 2002 http://www.senate.gov/~labor/Hearings-2002/april2002/041602wit/Peel.pdf
- NCVHS Panel, Testimony on Pharmacy Benefit Management Firms, May 20, 1999 http://www.ncvhs.hhs.gov/990520tr.htm

International Presentations

- Amsterdam Privacy Conference http://www.apc2012.org/ Panel with Ross Anderson on “The Role of Governments in Health Information Exchange”, October 8, 2012 http://www.apc2012.org/sites/default/files/pdffiles/APC%20programme_0.pdf

- RSI symposium on Management of Information Security, Montreal, Canada, Keynote Speaker, May 3, 2012 "Not even a Fig Leaf for Privacy: America's Health IT Systems and Data Exchanges" http://www.colloque-rsi.com/presentation/la-protection-de-la-vie-privee-dans-le-milieu-hospitalier-americain-et-des-enjeux-politiques-americains/
- ABA International Section Meeting, Dublin Ireland. Panel on "Evolving Standards for Obtaining Informed Consent for Genetic Research", October 11, 2011 http://www2.americanbar.org/calendar/section-of-international-law-2011-fall-meeting/Documents/PreMeetingBrochureMailer.Final.pdf
- Computers Privacy Data Protection, 4th International Conference on "European Data Protection: In Good Health?" Brussels, Belgium, Keynote Speaker, Jan 25, 2011 http://www.cpdpconferences.org/Resources/CPDP2011.pdf
- University of Cambridge, Computer Laboratory Security Seminar, "Across the Pond: An Update on Health Privacy and Health Data Security. How are American patients faring?" October 20, 2010 http://talks.cam.ac.uk/talk/index/27279
- World Health Summit, Working Session: Information Technology: New Horizons in Health Care, Berlin, Germany. October 12, 2010 http://www.worldhealthsummit.org/fileadmin/media/press/Press_Downloads/WHS%202010%20Final%20Program%20Print_online.pdf (see page 92-93)
- International Bar Association Technology Law Conference, The New Age of Health IT, "Data Privacy and Security, The Patient Perspective", Copenhagen, Denmark. May 26, 2010 http://www.intbar.org/conferences/conf326/binary/Copenhagen%20Technology%20Law%20programme.pdf
- 68th International Pharmaceutical Federation (FIP), FIP Pharmacy Information Section, "Patients in Control of Their Records, Uploading medical records to the Web: Threats and Opportunities", Basel, Switzerland, September 4, 2008 http://www.fip.org/CONGRESS/basel08/index.php?mod=congress&congress=program&program_id=147
- University of Cambridge, Computer Laboratory Security Seminar, "Electronic health records: which is worse, the UK system or the US System?", September 5, 2008 http://www.talks.cam.ac.uk/talk/index/13305

National Panel Presentations

- Computers, Freedom, and Privacy, CFP2013, Washington, DC. June 25, 2013, Moderated and organized the panel on "Medical Privacy in the Digital Age" http://www.cfp.org/2013/wiki/index.php/Main_Page
- American Psychiatric Association Annual Meeting, Symposium panel on "Electronic Health Record Privacy Update", May 7, 2012. http://www.psychiatry.org/
- Hofstra University Bioethics Center, Inaugural Conference on "The Ethical Use of Internet Cloud-Based Apps and Social Media in Healthcare" April 24, 2012 http://www.hofstra.edu/Community/culctr/culctr_events_ICASM.html#videos
- The Atlantic's Fourth Annual Health Care Forum, Washington, DC
  Panel 3: "Healthcare 2015 Can Big Data Be the Cure-All?" April 19, 2012 http://events.theatlantic.com/-2012-health-care-forum/2012/

- 2010 Genetic Alliance Annual Conference, Dinner Debate July 16, 2010 http://www.geneticalliance.org/conference2010.debate.deidentification
- CHIME CIO Forum "The National HIT Agenda - A Meaningful Town Hall Discussion", February 28, 2010 http://www.himssconference.org/docs/HIMSS10CIOForumBrochure.pdf
- The National Council for Prescription Drug Programs (NCPDP), *HIE and Pharmacy, "The Patient Perspective"*, February 2, 2010 http://www.newsmedical.net/news/20100122/NCPDP-announces-its-upcoming-Educational-Summit-Health-Information-Exchange-and-Pharmacy.aspx
- American Constitution Society, "Living Online - Privacy and Security Issues in a Digital Age", November 3,2009 http://www.acslaw.org/node/14610
- HIPAA Summit/Harvard Privacy Symposium Plenary Round Table, August 20, 2008
- HIMSS "View from the Top" keynote address, February 26, 2008 http://www.prolibraries.com/library/flash/serveflash.php?libname=himss&sessionID=87
- Harvard PCHIR 2007 Panel: Ethical, Legal, and Social Issues of PCHIRs, November 27, 2007
- Government Health IT: Security and Privacy for Electronic Health, October 10, 2007

Quoted in National Publications

The National Journal
Congressional Quarterly
The New York Times
The Washington Post
The Wall Street Journal
The Boston Globe
The Chicago Tribune
The LA Times
The Atlanta Journal Constitution
The Dallas Morning News
The Austin American Statesman
AP – various wire service stories
UPI – various wire service stories
Consumer Reports Magazine
PC World Magazine
USA Today
Fast Company Magazine
Smart Money Magazine
Bloomberg Businessweek
Wired News Magazine
Modern Healthcare Magazine
Government Health IT
Health IT News
Health Management Technology
BNA Healthcare Report
eMediaWire
Inside Health Policy
Federal Computer Week
eWeek
iHealthBeat
Kaiser Daily Health Policy Report
Computerworld
Next

National TV

- CNBC Nightly Business Report http://patientprivacyrights.org/2013/03/dr-peel-on-nightly-business-report-2/

- FOX Business News, The Willis Report http://patientprivacyrights.org/2013/03/dr-peel-on-the-willis-report/
- NBC Nightly News with Brian Williams http://patientprivacyrights.org/2013/03/dr-peel-on-nbc-nightly-news-with-brian-williams/
- ABC Good Morning America http://abcnews.go.com/GMA/video/cvs-health-insurance-weight-disclosure-requirement-employees-report-18770513
- ABC Nightly News with Diane Sawyer http://abcnews.go.com/WNT/video/cvs-employees-hand-medical-info-risk-penalty-18776450
- CNN OutFront with Erin Burnett http://patientprivacyrights.org/2013/03/dr-peel-on-cnns-outfront-with-erin-burnett/
- ABC TV Investigative Report "Your Medical Records May Not Be Private" September 13, 2012 http://abcnews.go.com/Health/medical-records-private-abc-news-investigation/story?id=17228986&singlePage=true#.UFKTXVHUF-Y
- KTVU, Oakland, CA, "Switch To Digital Medical Records Raises Concerns", July 16, 2010
  http://www.ktvu.com/news/24278317/detail.html
- FOX TV News "Dangers of Electronic Medical Records? Doctor is worried privacy concerns will lead to worse and more expensive medical treatment in the long run, March 26, 2010
  http://video.foxnews.com/v/4125807/dangers-of-electronic-medical-records
- PBS Online Newshour, "Military Digital Health Records System to be Model", April 9, 2009
  Video: http://www.pbs.org/newshour/video/module.html?mod=0&pkg=9042009&seg=2
  Written transcript: http://www.pbs.org/newshour/bb/military/jan-june09/militaryhealth_04-09.html
- FOX TV News Stuart Varney Show: Dangers of Online Medical Records March 5, 2009
  http://www.foxbusiness.com/video/index.html?playerId=videolandingpage&streamingFormat=FLASH&referralObject=3770856&referralPlaylistId=1292d14d0e3afdcf0b31500afefb92724c08f046&maven_referrer=staf

Honors and Awards

- Named one of the "Top Ten Influencers in Health Information Security" for 2012 by Healthcare Info Security:
  http://www.careersinfosecurity.com/top-10-influencers-in-health-infosec-a-5371
- Named one of the "100 Most Influential in Healthcare" in the US by ModernHealthcare magazine in 2007, 2008, 2009, and 2011—first privacy expert and consumer advocate on the list.
- Voted one of the "303 Best Doctors" in Austin Monthly magazine, January 2011
- HIPAA Summit XV, Distinguished Service Award, 2007
- Designated as one of the "Best Doctors in America," 2002 and 2005
- The Champions Award for Medical Privacy Advocacy, New Milestones Foundation, Austin, TX, October, 2006
- Commendation from the Senate of the State of Texas "For Her Outstanding Health Care Service to the People of Texas", March 11, 2002
- Distinguished Fellow of the American Psychiatric Association, 1986

Experience (private practice, education, administration, and medical privacy advocacy)

- Board of Directors, Electronic Privacy Information Center (EPIC), Washington, DC, 2009-
- Advisory Board, Electronic Privacy Information Center (EPIC), Washington, DC, 2006-2009
- Founder and Chair, Patient Privacy Rights Foundation, 2004 –
- President, Texas Society of Psychiatric Physicians, 2000-2001
- Chief of Psychiatry, Brackenridge Hospital, Austin, Texas, 1979-1990
- Founding Director, Department of Psychiatric Education, Central Texas Medical Foundation, Austin, Texas, 1981-1985
- Solo Private Practice of Psychiatry and Psychoanalysis, 1977-

Education

- Post-Residency: Graduate of the Dallas Psychoanalytic Institute, 1999
- Psychiatric Residency: University of Texas Medical Branch Galveston, 1974-1977
- University of Texas Medical Branch at Galveston 1970-1974, M.D. degree
- University of Texas at Austin, attended 1968-1970

Licensure and Board Certification

- Board certification by the American Board of Psychiatry and Neurology, 1979
- Licensed to practice Medicine in Texas, 1974